

Sub
G2 cont
2
D. Legend
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RH Antagonist, follicle [development] growth is not externally stimulated but maintained by endogenous gonadotropins.

Sub
G2 cont
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19. (Twice Amended) The method according to claim 18 wherein after [the inhibition of the action of natural] suppression of endogenous LH caused by Cetorelix, [the] follicle [development] growth is not externally stimulated but maintained by endogenous gonadotropins. NPL

REMARKS

Claims 15, 16, 18-24 and 26-33 are pending. The claims have been amended to overcome an indefiniteness rejection and objection, and not to distinguish from any prior art. Reconsideration is requested.

Claim 18 was rejected under 35 USC § 112, second paragraph, as being indefinite. Claims 18 and 19 have been amended as helpfully suggested by the Examiner and are believed to be free of the rejection.

Claims 21-22 and 33 stand rejected under 35 USC § 102 as being anticipated by Diedrich et al. This rejection is traversed for the following reasons.

Claims 21-22 and 33 recite an improved dosage regimen in which Cetorelix is applied starting cycle day 1 to 10 and ovulation can be induced between day 9 to 20 of the menstruation cycle or in which Cetorelix is applied starting cycle day 4 to 8 and ovulation can be induced between day 9 and 20 of the menstruation cycle. There is no teaching in the cited reference of these specific regimens. Accordingly,

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the reference fails to teach each and every element of the claimed invention, as is required for a rejection under 35 USC § 102. Withdrawal of the rejection is respectfully requested.

Claims 15, 16, 18-24 and 26-33 stand rejected under 35 USC § 103(a) as being unpatentable over Diedrich et al. in view of Felberbaum et al. The Examiner found the Declaration filed November 23, 1998 to be unpersuasive. Applicants note once more that the authorship of the Felderbaum article includes one of the present inventors. Although certain aspects of the invention may be disclosed in the article, the complete invention is not disclosed therein.

Applicants submit that the presently claimed invention is distinguished from the Felderbaum article in the following:

Cetrorelix was introduced in the study IVF program to examine whether it is possible to avoid premature LH surge and to lower the interference with the hypothalomo-hypophysial-ovarian axis. The study design describes two different dose regimes with 3 mg Cetrorelix s.c. daily, from day 7 until ovulation induction. Premature LH surge could be avoided in both dosages. Nothing is reported about FSH level remaining in a physiological range. This regime is therefore only representative of certain aspects of the invention. In this respect, K. Diedrich is both an author of the article and an inventor of the present claims. The other authors, who are not named as inventors, did not contribute to the invention but carried out the clinical work according to instructions from the inventors.

However, the invention further represents the elaboration of a clinically

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practicable therapeutic regime, which is due to the contribution of the other inventors who are not named authors on the publication. This is represented by the development of a single or dual dose posology including 1-10, preferably 2-6 and most preferably 3 mg Cetrorelix on cycle day 6 and a multiple dose posology which represents a dose of 0.1-0.5, preferably 0.25 mg Cetrorelix also on cycle day 6. In the Felderbaum article, Cetrorelix is administered on day 7 in a dosage of 3 mg or 1 mg daily up to ovulation. It is submitted that this is a remarkable difference in dose and management of IVF therapy. Therefore, it is respectfully submitted that the Felderbaum reference is not prior art in view of the previously filed Declaration and the fact that publication was made less than one year prior to the priority date of the present application. It is further submitted that the combination of the Felderbaum reference with Diedrich would not result in the presently claimed invention. Accordingly, withdrawal of the rejection is respectfully requested.

Claims 15, 16, 18-24 and 26-33 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending application 09/053,152. This rejection is noted and Applicants will consider filing a Terminal Disclaimer if the '152 application is allowed prior to the present application.

Claims 21 and 22 have been rejected as claiming the same invention as that claimed in claims 34 and 35 of "prior U.S. Pat. No. 09/053,152". It appears that this should also be a provisional rejection, as the '152 application has not yet been patented. Clarification is requested.

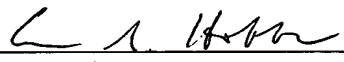
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Claim 15 has been objected to as being awkwardly written. Claim 15 has been amended as helpfully suggested by the Examiner.

All objections and rejections having been addressed, it is submitted that the application is in condition for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted,

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